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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,171	08/31/2004	Kanako Suzuki	040432	5261

23850 7590 06/13/2007

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EXAMINER	
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ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,171	SUZUKI ET AL.	
	Examiner	Art Unit	
	Catherine S. Hibbert	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *4,5,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-12 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *31 August 2005; 31 August 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the First Office Action on the Merits of the Application filed 31 August 2004, which claims benefit of the International Application PCT/JP03/02401 filed 28 February 2003. The Applicant's entry of the Preliminary Amendments on 31 August 2004 is acknowledged. Claims 1-19 are pending. Claims 4, 5, and 13-14 are withdrawn to non-elected subject matter. Claims 1-3, 6-12 and 15-19 are under examination.

Election/Restrictions

Applicant's election without traverse of Group I and of "at the 3'-end side that is downstream to a SRE region existing in the promoter region" (claim 7) and "SEQ ID No. 4" (claims 3-5) in the reply filed on 23 March 2007 is acknowledged.

Claims 4, 5, and 13-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 March 2007.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicant's claim to Foreign Priority for PCT/JP03/02401 filed on 28 February 2003, which claims priority to JP2002-55853 (1/3/2002) and JP2002-354670 (6/12/2002), is acknowledged.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "SRE region" in claim 7 is a relative term which renders the claim indefinite. The term "SRE region" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification regards both SEQ ID NOs 6 and 7 as SRE. In addition, the specification refers to SREs having additional base changes. Furthermore, the sequence for the term SRE in the relevant state of the art has been described as the DNA sequence "5'-

TAGGGGCGGAAATTTA-3" or as small as the conserved region "5'-GGAAATT-3'" (see especially abstract and p.235, ¶1, lines 1-13 in Tani et al, ("A novel nuclear factor, SREB, binds to a cis-acting element, SRE, required for inducible expression of the Aspergillus oryzae Taka-amylase A gene in A. nidulans" in Mol Gen Genet :2000, 263:p.232-238). In addition, the term SRE "region" could be read broadly to include any DNA sequence containing any part of an SRE sequence, which could be as small as a single nucleotide from an SRE sequence. Therefore, the metes and bounds of applicant's invention in claim 7 can not be determined and claim 7 is properly rejected.

The term "DNA fragment obtained by partial modification of the DNA fragment" in claim 11 is a relative term which renders the claim indefinite. The term "obtained by partial modification" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, the term "partial modification" could refer to partial nucleotide base changes and/or to "partially digestion of the DNA sequence" and therefore the metes and bounds of the applicant's invention in claim 11 can not be determined and claim 11 is properly rejected.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7, 11-12, and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Boel et al (US Patent No. 5,536,661: issued 16 July 1996).

Claim 1 is directed to a modified promoter constructed by inserting a first DNA fragment including CCAATNNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including CGGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter capable of functioning in a filamentous fungus.

Boel et al teaches construction of a vector comprising a "TAKA-amylase promoter or functional parts thereof" for expression of a protein in Aspergillus (see especially abstract, lines 10-13). Boel et al further teaches wherein the promoter contains a first base sequence "CCAATTAGAAG" and a second base sequence "CGGAAATTTAAAGG" that are arranged sequentially from the 5'-end side to the 3'-end side of said promoter (see especially sequence of Figure 1, lines 17-19 and Boel et al claims 1-4), which meets the limitations of the instant claims 1-3, 6 and 11.

Claim 7 is directed to the modified promoter of claim 6, wherein said first DNA fragment and said second DNA fragment are inserted at the 3'-end side that is downstream to a SRE region existing in the promoter region. A broad, reasonable interpretation of an "SRE region" could read on the nucleotide sequence "5'-ATTTAAAG-3'" which is contained in an SRE consensus sequence (see instant application Seq ID No. 6). Boel et al teaches the sequence "5'-ATTTAAAG-3'" which is upstream to the said first and second DNA sequences and therefore anticipates the limitations of claim 7.

In addition, Boel et al teaches the modified promoter of claim 1, and further teaches wherein said promoter capable of functioning in a filamentous fungus is a promoter of Taka-amylase of Aspergillus oryzae (claim 12). Furthermore, Boel et al teaches a vector in which the modified promoter of claim 1 is integrated (claim 15) and a structural gene of a targeted protein is integrated under control of the modified promoter (claim 16) and further teaches wherein a transformed filamentous fungus comprises the vector and is capable of expressing said structural gene(claims 17-18), and producing a protein by culturing the filamentous fungus of claim 18 under conditions capable of producing protein; and collecting the produced protein (claim 19).

For example, Boel et al recites "the gene for the desired product functionally linked to promoter and terminator sequences may be incorporated in a vector containing the selection marker" or may be placed on a separate vector or plasmid "capable of being integrated into the genome of the host strain" (col. 12, ¶ 1, lines 1-5). In addition, Boel et al teaches the Taka-amylase promoter and collection of produced protein by accumulation of expressed protein in cells, followed by cell disruption, or preferably, by collection of expressed proteins after proteins are secreted from host cells (col. 11, ¶ 2, lines 1-6 and abstract, lines 1-17 and Boel et al claim 5).

Therefore, Boel et al teaches all the limitations of claims 12 and 15-19.

Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Minetoki et al [("Improvement of promoter activity by the introduction of multiple copies of the conserved region III sequence, involved in the efficient expression of *Aspergillus*

oryzae amylase-encoding genes" in Appl Microbiol Biotechnol, 1998:50 p.459-467) made of record in the IDS].

Minetoki et al teaches wherein a plurality of said first DNA fragments and a plurality of said second DNA fragments are inserted (claim 8), and further to wherein the same number of said first DNA fragments and said second DNA fragments are inserted (claim 9), and further teaches to wherein one first DNA fragment and one second DNA fragment are combined as a pair, and in each pair, said first DNA fragment and said second DNA fragment are inserted so that the first DNA fragment is located at the 5'-end side of said promoter (claim 10).

For example, Minetoki et al teaches modification of the promoter for the Aspergillus oryzae amyB gene (see title and abstract). Furthermore, Minetoki et al teaches inserting multiple copies of Region IIIa sequence which contains the second base sequence "CGGAAATTTAAAGG" inserted in tandem with the Region IIIb sequence which contains the first DNA fragment including the "CCAATNNNNNN" sequence into the promoter region of a modified vector (see especially Figure & legends 1 and 2). Since the sequence "CGGAAATTTAAAGG" also reads on a full-length SRE region (described above), the Minetoki et al reference meets all of the limitations of claims 7-10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert whose telephone number is 571-

270-3053. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner: Catherine S. Hibbert

MARY MOSHER
SUPERVISORY PATENT EXAMINER
6-8-07